IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

In re:	:	**MDL Docket No. 4:03CV1507-WRW**
	:	**4:05CV00163**
PREMPRO PRODUCTS LIABILITY LITIGATION	:	
	:	
LINDA REEVES	:	**PLAINTIFF**
v.	:	
WYETH, et. al.	:	**DEFENDANTS**

ORDER

Pending is Defendant's Motion for Summary Judgment re: the Learned Intermediary/ Proximate Causation (Doc. No. 54). Plaintiff has responded and Defendant has replied.[1] Also pending is Defendant's Motion for Summary Judgment re: Specific Claims (Doc. No. 61). Plaintiff has responded and Defendant has replied.[2] The parties presented oral arguments on June 22-23, 2006. Supplemental briefs on the learned intermediary issue were also filed.[3] Additionally, Defendant's filed a Renewed Motion for Summary Judgment on the Statute of Limitations (Doc. No. 162).

[1]Doc. Nos. 104, 123.

[2]Doc. Nos. 81, 121.

[3]Doc. Nos. 156, 168, 170.

I. BACKGROUND

Plaintiff took prescription hormone replacement therapy ("HRT") because she was at high risk for osteoporosis.[4] Plaintiff alleges that ingestion of HRT medications caused her to develop breast cancer. Plaintiff asserts negligence,[5] design defect, fraud, and failure to warn.[6]

II. SUMMARY JUDGMENT STANDARD

Summary judgment is appropriate only when there is no genuine issue of material fact, so that the dispute may be decided on purely legal grounds.[7] The Supreme Court has established guidelines to assist trial courts in determining whether this standard has been met:

> The inquiry performed is the threshold inquiry of determining whether there is the need for a trial -- whether, in other words, there are any genuine factual issues that properly can be resolved only by a finder of fact because they may reasonably be resolved in favor of either party.[8]

The Court of Appeals for the Eighth Circuit has cautioned that summary judgment is an extreme remedy that should only be granted when the movant has established a right to the judgment beyond controversy.[9] Nevertheless, summary judgment promotes judicial economy by

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[4]Doc. Nos. 67 and 90 (Plaintiff also contends that she took HRT because of "illusory cardiac benefit.").

[5]More specifically failure to test.

[6]Doc. No. 11. Plaintiff conceded her negligence per se, breach of warranty, and negligent misrepresentation claims at the June22, 2006 hearing; therefore those claims are withdrawn.

[7]*Holloway v. Lockhart*, 813 F.2d 874 (8th Cir. 1987); Fed R. Civ. P. 56.

[8]*Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986).

[9]*Inland Oil & Transport Co. v. United States*, 600 F.2d 725, 727 (8th Cir. 1979).

preventing trial when no genuine issue of fact remains.[10] I must view the facts in the light most favorable to the party opposing the motion.[11] The Eighth Circuit has also set out the burden of the parties in connection with a summary judgment motion:

> [T]he burden on the party moving for summary judgment is only to demonstrate, *i.e.*,"[to point] out to the District Court," that the record does not disclose a genuine dispute on a material fact. It is enough for the movant to bring up the fact that the record does not contain such an issue and to identify that part of the record which bears out his assertion. Once this is done, his burden is discharged, and, if the record in fact bears out the claim that no genuine dispute exists on any material fact, it is then the respondent's burden to set forth affirmative evidence, specific facts, showing that there is a genuine dispute on that issue. If the respondent fails to carry that burden, summary judgment should be granted.[12]

Only disputes over facts that may affect the outcome of the suit under governing law will properly preclude the entry of summary judgment.[13]

III. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT RE: THE LEARNED INTERMEDIARY/ PROXIMATE CAUSATION

A manufacturer's duty to warn generally extends to the ultimate user of a product; however, the learned intermediary doctrine is an exception to this rule.[14] The learned intermediary doctrine "provides that a drug manufacturer may rely on the prescribing physician to warn the ultimate consumer of the risks of a prescription drug [because] [t]he physician acts as

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[10] *Id.* at 728.

[11] *Id.* at 727-28.

[12] *Counts v. MK-Ferguson Co.*, 862 F.2d 1338, 1339 (8th Cir. 1988) (*quoting City of Mt. Pleasant v. Associated Elec. Coop.*, 838 F.2d 268, 273-74 (8th Cir. 1988) (citations omitted)).

[13] *Anderson*, 477 U.S. at 248.

[14] *West v. Searle & Co.*, 806 S.W.2d 608, 614 (Ark. 1991).

the 'learned intermediary' between the manufacturer and the ultimate consumer."[15] Therefore, if an adequate warning is provided to the prescribing physician, the manufacturer is relieved of its duty to warn the patient, regardless of what the physician communicated to the patient. In circumstances where a manufacturer fails to adequately warn the physician, the failure to warn "is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that the adequate warning should have communicated."[16]

Defendant contends that Plaintiff cannot establish that "the alleged failure to warn or misrepresentations were the proximate cause of their breast cancer,"[17] because:

> Plaintiff's doctors and the rest of the medical community already knew that breast cancer was a risk associated with hormone therapy when they prescribed it to [Plaintiff] . . . WHI did not change what doctors already knew about the relative and absolute risk of breast cancer in women using hormone therapy . . . .[18]

Additionally, Defendant asserts that because Dr. Caldwell testified that, knowing everything he knows today, he still would have prescribed HRT to Plaintiff, she is unable to establish that "but for the inadequate warning, the treating physician would not have used or prescribed the product."[19]

Plaintiff contends that Dr. Caldwell's testimony that, knowing what he knows today, he still would have prescribed her HRT, is subject to a credibility determination because it is

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[15]*Id.*

[16]*Ehis v. Shire Richwood, Inc*., 367 F.3d 1013, 1016 (8th Cir. 2004) (*quoting Christopher v. Cutter Labs*, 53 F.3d 1184, 1192 (11th Cir. 1995).

[17]Doc. No. 55.

[18]*Id.*

[19]*Id.*

"controverted with objective circumstantial evidence."[20] Additionally, Plaintiff asserts that while Dr. Caldwell may have known of the association of HRT and breast cancer, his knowledge "was nowhere near the information contained in the 2005 Prempro label."[21]

A. Prescribing HRT Anyway

Defendant's focus on Dr. Caldwell's testimony that, even with the 2005 label,[22] he still would have prescribed HRT, paints with too broad a stroke. The issue is not whether Dr. Caldwell still would have prescribed HRT to Plaintiff; rather, would he have prescribed it to Plaintiff in the same amount, and for the same length of time -- both key points in Plaintiff's case. In fact, Dr. Caldwell testified that today his practice is to prescribe HRT at the lowest dose for the shortest duration, and this was not his practice before July 2002.[23] So, a material question of fact remains in dispute i.e., whether Dr. Caldwell would have prescribed HRT in the dosages and for the lengths of time if he knew then what he knows based on the 2005 HRT label.

Additionally, I'm not convinced that a physician's testimony regarding what he or she would have done in 20/20-hindsight should be considered absolute. It appears to me that such testimony may well hinge on credibility, which is for the jury decide. I'm inclined to hold with the idea that "unless a physician's claim that she would have prescribed a drug even if adequately warned is self-disserving, the credibility of such a claim is generally a jury question not to be resolved on a motion for summary judgment."[24]

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[20]June 22, 2006 Tr. at 50.

[21]Doc. No. 104.

[22]Plaintiff asserts that the 2005 label is adequate.

[23]Doc. No. 67, Ex. 5.

[24]*Golod v. La Roche*, 964 F. Supp. 841, 857 (S.D.N.Y. 1997).

B. Independent Knowledge

Defendant contends that since Dr. Caldwell had independent knowledge of a connection between breast cancer and HRT, Plaintiff cannot establish the causation element of her failure to warn claim. Defendant's assertion is not on the mark. To break the causal link between Plaintiff's injury and the alleged failure to warn, Dr. Caldwell must have had "*substantially the same knowledge* as an adequate warning from the manufacturer should have communicated."[25]

Although Dr. Caldwell had knowledge of relationship between HRT and breast cancer, it cannot be said, based on the information submitted to date, that he had substantially the same knowledge that the 2005 label contained when he prescribed HRT to Plaintiff. Among other things, Dr. Caldwell admitted that the WHI study, which is discussed in the 2005 label, revealed a breast cancer risk higher than he had previously thought.[26]

Because Defendant has failed to establish that Dr. Caldwell had substantially the same knowledge that the 2005 label contained when he prescribed HRT to Plaintiff, summary judgment cannot be granted under the learned intermediary doctrine.

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[25]*Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) (emphasis added) (citations omitted). *See also Garside v. Osco Drug, Inc.*, 976 F.2d 77, 83 (1st Cir. 1992) (Holding that a physician's testimony must "show unequivocally that s/he knew at the relevant time *all* the information which would have been included in a proper warning.") (emphasis in original).

[26]Doc. No. 67, Ex. 5 at 84.

IV. DEFENDANT'S MOTION FOR SUMMARY JUDGMENT RE: SPECIFIC CLAIMS

A. Design Defect

Defendant contends that Plaintiff cannot maintain a design defect claim because Plaintiff is not disputing the design of Prempro, but, rather, whether Wyeth properly warned about Prempro risks. More specifically, Defendant asserts that because Plaintiff does not think Prempro should be pulled from the market, it is not defectively designed, and Plaintiff cannot maintain her cause of action.

In opposition, Plaintiff asserts she is advocating a drug with different composition and volumes of estrogen and progestin (not necessarily different chemicals), which constitutes a change in design.[27] Plaintiff also contends that Defendant's actions regarding the low-dose Prempro suggest that the low-dose drug is considered a different product than that high dose drug. For example, Wyeth sought patent protection for low-dose Prempro and proposed another name for the low-dose Prempro -- Premia.[28]

It seems to me that the evidence supports Plaintiff's position that low-dose Prempro is a different drug than high-dose Prempro. In addition to the fact that Wyeth sought separate patent protection, and wanted to re-name the low-dose Prempro, I also think it is significant that the low-dose Prempro uses different ratios of estrogen to progestin -- which indicates that the low-dose Prempro is designed differently. Accordingly, Wyeth's motion is DENIED as to the design defect claim.

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[27]Doc. No. 84. *See also* June 23, 2006 Tr. at 129.

[28]Doc. No. 84.

B. Failure to Test

Defendant contends that Plaintiff's "failure to test" claims should be dismissed because no such independent cause of action exists in Arkansas.[29] Plaintiff asserts that the "failure to test" claim is simply a component of her failure to warn and negligence claims.[30] I agree, so evidence of "failure to test" will be received in connection with the negligence and failure to warn claims. Defendant's Motion is DENIED as to the failure to test evidence.

C. Negligent Failure to Warn

Defendant contends that it had no duty to warn of injuries that Plaintiff did not suffer.[31] Although styled as a Motion for Summary Judgment, Defendant's motion appears to be a motion *in limine* to preclude Plaintiffs from presenting evidence of failure to warn of harms that were not suffered by Plaintiff -- in other words, Defendant contends that Plaintiff should be allowed to only present evidence as to Defendant's failure to warn of breast cancer risks.

While there is case law to support both sides of this debate, I believe the better practice is to permit Plaintiff to present evidence of failure to warn of harms that she has not suffered. In *Cipollone v. Liggett Group, Inc.*,[32] the court held that:

> evidence of diseases other than those contracted by [the plaintiff] is relevant to the existence of [the defendant's] duty to warn as to these diseases. If there are numerous risks from cigarette smoking, the mere fact that plaintiff suffered from only one does not limit defendants' duty to warn to that risk alone. The adequacy of the warning depends upon all of the risks encountered by the average consumer. A plaintiff may well argue that had she or he been warned of all the risks, cigarettes would have been

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[29]Doc. No. 62.

[30]Doc. No. 84.

[31]Doc. No. 62.

[32]*Cipollone v. Liggett Group, Inc.*, Civ. A. No. 83-2864, 1987 WL 14666 (D.N.J. Oct. 27, 1987).

> avoided. The fact that only one of the risks manifested itself does not, as a matter of law, relieve defendants of their duty to warn of the others.[33]

Based on this, Defendant's Motion is DENIED. Of course, the burden remains on Plaintiff to establish a causal connection between the alleged failure to warn of injuries which she has not suffered and her breast cancer.

V. DEFENDANT'S RENEWED MOTION FOR SUMMARY JUDGMENT ON THE STATUTE OF LIMITATIONS

After deposing Plaintiff's husband on June 28, 2006, Defendant filed a renewed motion for summary judgment on the statute of limitation. Defendant contends that Mr. James Reeves's testimony contradicts Plaintiff's testimony regarding when she became aware of the connection between her breast cancer and HRT medications. If anything, Mr. Reeves testimony raises questions of material fact, which a jury is to decide. Therefore the motion is DENIED. Of course, this order does not prevent Defendant from raising the issue again at trial.

CONCLUSION

Based on the findings of fact and conclusions of law about, I rule as follows:

1. Defendant's Motion for Summary Judgment re: the Learned Intermediary/ Proximate Causation (Doc. No. 54) is DENIED

2. Defendant's Motion for Summary Judgment re: Specific Claims (Doc. No. 61) is DENIED.

3. Defendant's filed a Renewed Motion for Summary Judgment on the Statute of Limitations (Doc. No. 162) is DENIED

IT IS SO ORDERED this 11th day of July, 2006.

/s/ Wm. R.Wilson,Jr.
UNITED STATES DISTRICT JUDGE

[33] *Id* at *4.